

REMARKS

Claims 1-42 constitute the pending claims in the present application. Among them, claims 19-39 are withdrawn from further consideration by the Examiner as being drawn to non-elected inventions. Applicants will cancel these claims upon indication of allowable subject matter. Claims 1-18, 40-42 constitute claims currently being considered by the Examiner.

This supplemental reply provides additional arguments that addresses claim rejections under 35 U.S.C. 102(b), and is to be considered in conjunction with, rather than in place of, the arguments presented in the Submission of RCE filed on March 6, 2003. Applicants respectfully request reconsideration in view of the following remarks.

*Claim rejections under 35 USC §102(b)*

Claims 1-5, 10, 11, 15, 16, 40 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/19574.

Applicants submit that WO 96/19574 does not anticipate the claimed invention because WO 96/19574 ("574" thereafter) is non-enabled for the claimed *in vivo* treatment methods. Based on ample evidence, Applicants have argued in the Submission for RCE filed on March 6, 2003 that '574 is not enabled for the claimed *in vivo* treatment method. Applicants provide additional arguments here to support the notion that an anticipatory reference must be enabling.

Pursuant to MPEP 2121.01, "In determining that quantum of prior art disclosure which is necessary to declare an applicant's invention 'not novel' or 'anticipated' within section 102, the stated test is whether a reference contains an 'enabling disclosure'... . *In re Hoeksema*, 399 F.2d 269, 158 USPQ 596 (CCPA 1968). A reference contains an 'enabling disclosure' if the public was in possession of the claimed invention before the date of invention.' Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his [or her] own knowledge to make the claimed invention.' *In re Donohue*, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985)."

Indeed, *In re Donohue* establishes that “[i]t is well-settled that prior art under 35 U.S.C. 102(b) must sufficiently describe the claimed invention to have placed the public in possession of it. Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his own knowledge to make the claimed invention. Accordingly, even if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it was not enabling” (emphasis added), *In re Donohue*, 766 F.2d 531226 USPQ 619 (Fed. Cir. 1985). Also see *Chester v. Miller*, 906 F.2d 1574, 15 USPQ2d 1333 (Fed. Cir. 1990). In addition, “...a prior art reference must be ‘considered together with the knowledge of one of ordinary skill in the pertinent art’” (emphasis added). *In re Paulsen*, 30 F.3d 1475, 31 USPQ2d 1671 (Fed. Cir. 1994).

Applicants submit the criteria set forth above is what separates invention from fiction. Applicants submit that a skilled artisan could not have combined the disclosure of the '574 application with the common knowledge of IL-11 signaling in osteoclast and osteoblast to make the claimed invention. Thus, the '574 application fails to place the public in possession of the claimed invention, as is legally required for “anticipation.”

Specifically, if a skilled artisan were to combine the disclosure of the '574 application and the common knowledge that IL-11 signaling in all tested cells (including *both* osteoclast and osteoblast) stimulates cell proliferation, the skilled artisan would not be certain if the final outcome of blocking the function of both osteoclast and osteoblast with anti-IL-11R Ab (or anti-IL-11 Ab) would result in a net positive, negative, or mutually canceling effect in bone density (see detailed scientific background described in the Submission to RCE filed on March 6, 2003).

"Anticipation" in the patent sense means that the subject matter was previously known. A general suggestion that, in view of the common knowledge, *may or may not succeed* in practicing the novel method, a method that has not previously been shown that it would work as intended, does not convert the suggested *hypothetical method* into a previously *existing method*. This is especially so when the common knowledge seems to contradict the prediction of a cited "prior art." A general recipe of uncertain success is nothing more than an invitation for further experimentation with no assurance of success, and it does not convert a hoped-for product into one that previously existed.

Until the Applicants' unexpected discovery that IL-11 signaling in osteoblast actually inhibits (rather than stimulates) osteoblast function, a skilled artisan would not know whether blocking IL-11 signaling in both osteoblast and osteoclast would *certainly* (rather than *probably* or *possibly*) result in a net positive, negative or mutually canceling effect on bone density. Applicants' unexpected discovery first allow a skilled artisan to conclude that simultaneous blocking of IL-11 signaling in both osteoclast and osteoblast would increase bone formation while decreasing bone loss, resulting in a net inhibition of bone density reduction (or, in certain favorable conditions, resulting in a net bone density increase). Therefore, it is the instant application that first truly overcomes the prior art uncertainty of inhibiting both osteoclast and osteoblast function, and enables a skilled artisan to practice the claimed invention.

From a different perspective, if the Examiner were examining '574, the disclosure of '574 must satisfy the enablement requirement of 35 U.S.C. 112, first paragraph. The test for enablement is whether a skilled artisan, in view of the disclosure of the specification and common knowledge in the field, can practice the claimed invention without undue experimentation. Factors to be considered in assessing enablement is set forth in *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), which includes state of the art, level of predictability, existence of working examples, amount of direction or guidance by the inventor, etc.

When analyzing such factors relating to enablement, the Examiner would conclude that the disclosure of '574 is non-enabling, since the state of the art (IL-11 signaling in all cells stimulates cell proliferation) casts a significant doubt on the *in vivo* treatment method disclosed in the '574 application. A skilled artisan would face utter unpredictability when practicing the *in vivo* method of '574, especially in view of the fact that '574 provides no working example and barely any guidance by the "inventor" (two general sentences spanning pages 6-7). Thus, undue experimentation would be needed to practice the alleged invention of '574.

In summary, WO 9619574 is non-enabling for the claimed *in vivo* treatment method, and thus does not satisfy the legal requirement for anticipation. Reconsideration and withdrawal of rejection under 35 U.S.C. 102(b) is respectfully requested.

**CONCLUSION**

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to Deposit Account No. 18-1945.

Respectfully Submitted,

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